This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92
Date Prepared June 15, 1999

510(k) number: _____ JUN 23 2000

Applicant Information:
Vivant Medical, Inc.
3210B Alpine Road
Portola Valley, CA. 94028

Contact Person: Jack W. Moorman
Phone Number: (650) 529-1238
Fax Number: (650) 529-1229

Device Information:
Classification: Class II
Trade Name: VMI Biopsy Marker System
Classification Name: Implantable Staple (21 CFR 878.4750)

Equivalent Device:
The subject device is substantially equivalent in intended use and/or method of operation to the Ethicon MicroMark II Tissue Marker (K970817) and the USSC Auto Suture Site Marker (K983400)

Intended Use:
The VMI Biopsy Marker System is intended for use during percutaneous breast biopsy procedures to radiographically mark the surgical location. It is intended for use with Ethicon Mammotome 11 GA Probes (product code P1175).

Test Results:
Performance
Results of in-vitro testing demonstrate that the VMI Biopsy Marker System is safe and effective for its intended use.

Biocompatibility
Results of testing demonstrate that the VMI Biopsy Marker is biocompatible.

Summary: Based on the intended use, product, performance and biocompatability information provided in this notification, the subject device has been shown to be substantially equivalent to the currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 23 2000

Mr. Jack Moorman
President
Vivant Medical, Inc.
3210-B Alpine Road
Portola Valley, California 94028

Re: K000278
Trade Name: Vivant Medical Biopsy Marker
Regulatory Class: II
Product Code: FZP
Dated: May 3, 2000
Received: May 5, 2000

Dear Mr. Moorman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Lochner

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K000278

Device Name: Vivant Medical Biopsy Marker

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diane R. Kochner

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000278

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-the Counter Use _____

(Optional Format 1-2-96)